

Smoke Free Policy

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1. Summary

- 1.1 United Lincolnshire Hospitals NHS Trust (ULHT) as a healthcare provider and major employer in Lincolnshire will set an example to other organisations, promote public health and create an environment that minimises the health risks to members of the public, patients and staff who access or provide our services.
- 1.2 ULHT endorses the principle that whilst smoking is a matter of personal choice and that not all smokers will wish to cease smoking, where an individual smokes is of public concern. ULHT acknowledges that breathing other people's smoke is both a public health hazard and a welfare issue. Therefore, the Smoke Free policy has been adopted.
- 1.3 The organisation is carrying out its duty of care as an employer and complying with current Health and Safety legislation; this policy has been created in line with the requirements of, but not limited to NICE Guidance - Smoking cessation in secondary care: acute, maternity and mental health services - November 2013; Health Act 2006, which prohibited smoking in public places from 1 July 2007; Health & Safety at Work etc Act 1974 Section 2 (2) (e) - to provide a working environment that is safe and without risk to health; The Management of Health and Safety at Work Regulations 1999 - to assess risks to health, safety and welfare in the workplace; The arrangements for the Health and Safety at Work - Pregnant Workers Directive (92/85/EEC), to protect employees that are pregnant, have recently given birth or who are breastfeeding.
- 1.4 As well as its duty to protect the health of employees, patients and visitors, ULHT also has a duty to safeguard its property. Therefore this policy is also intended to minimise the risk of fire caused by smoking in unauthorised areas.
- 1.5 ULHT will actively encourage, promote and support smoking cessation amongst employees, patients, visitors and members of the general public. It is recognised that some employees may experience difficulty in complying with this policy. Any employee who is considering stopping smoking can access information and support through the Trust's Occupational Health Service. This may take a variety of forms including: the provision of information and guidance; counselling; in-house smoking cessation programmes and referral to Stop Smoking Services.

2. Introduction

2.1 Purpose

- 2.1.1 To exercise the organisation's statutory role in promoting and maintaining the health of employees, patients, visitors and members of the general public and to extend its health philosophy to the work environment which it manages.

2.2 Context

- 2.2.1 The organisation is carrying out its duty of care as an employer and complying with current Health and Safety legislation.

2.3 Objectives

- 2.3.1 To ensure that all staff, patients and visitors including contractors clearly understand their obligations. To protect all employees, patients, visitors and members of the general public who access any site or enter any establishment or enclosed space owned or used by the organisation for any undertaking whatsoever, from exposure to second hand smoke. (To include any site or establishment currently sublet, rented or leased from ULHT, to other government/NHS organisations). To be an exemplary employer, as well as an exemplary public organisation, in protecting people from the health risks of passive smoking. To encourage a healthier workforce that recognises the benefits of a smoke free environment. To ensure legal compliance.

2.4 Scope

- 2.4.1 This policy applies to all Trust employees, patients, visitors, members of the general public and third party users of the site.

2.5 Compliance

- 2.5.1 This policy complies with the legislation, standards, guidelines, codes of conduct, and any other relevant document listed in the Referenced Documents' section.

3. Roles and Responsibilities

The policy has the support of the Trust Board, Staff and Health & Safety representatives. Its successful application is dependent upon the full support of all staff. It also requires acceptance by patients, visitors and the wider community.

3.1 Managers' Responsibilities

3.1.1 All members of staff who have managerial or supervisory responsibility will ensure staff who report to them understand and comply with this policy; Fully support staff who bring this policy to the attention of any person in breach of it by reinforcing the smoke free message and by intervening in situations that become difficult for the staff member to handle.

3.1.2 Fully support any members of staff who wish to cease smoking by referral for stop smoking assistance, providing adequate cover when staff attend such sessions so that the Trust's work, and especially clinical care, can continue uninterrupted; Monitor policy application in their ward, department or associated work area(s); Ensure their department is adhering to the policy.

3.2 Staff Responsibilities

3.2.1 All staff are to be familiar with this policy in order to contribute towards its application; To politely remind patients and visitors of the smoke-free policy if they consider them to be in breach of the policy by smoking in the organisation's premises including the grounds. The Trust do not want anyone to feel that they need to engage in difficult or challenging situations and should not approach individuals (whether staff or patients) to ask them to stop smoking unless they are confident and feel that it is safe to do so.

3.2.2 To recognise that smoke lingers on breath and clothes and that patients and other staff may find this offensive; To offer routine brief advice to smokers regarding support to quit. All staff to be aware that they may face disciplinary action should they be found transgressing this policy.

3.2.3 The first step in treating tobacco dependence is to identify current tobacco users. Ask every patient if they currently smoke tobacco. Record smoking status in Current Physical Health Assessment. All in patients will be Screened for smoking status and this this will be recorded in the patient records, clearly and consistently.

3.2.4 All eligible patients will be given very brief advice and an offer of support to comply with the Trust's Smoke free Policy and the NICE guidelines for smoking cessation in secondary care smokers will need to abstain from smoking whilst in Trust buildings and grounds during an inpatient admission.

3.2.5 Making an attempt to permanently stop smoking is an opportunity not an obligation.

3.2.6 Every smoker should be offered Medication/NRT to manage their tobacco dependence in a reasonable time on arrival to an inpatient unit. This should be followed up by the offer of tobacco dependence treatment support from the stop smoking service.

3.2.7 Offering support to quit or manage tobacco withdrawal symptoms during a period of temporary abstinence, rather than asking a smoker how interested are they in stopping or telling a person they should stop, leads to more people making a quit attempt.

- 3.2.8 The most effective method of quitting or managing tobacco withdrawal symptoms during a period of temporary abstinence, is with combination NRT (i.e. a patch and oral product) and behavioural support. Advising the smoker that stopping smoking is one of the best things they can do for their health and wellbeing is recommended by the Department of Health. Please see **Appendix 1**.
- 3.2.9 Patients who insist on leaving the ward areas to smoke will be advised that it will be noted in the patient record that they have been advised and will need to leave the hospital site completely before smoking.
- 3.2.10 Remind the patient of the smoke free policy and make sure they have been offered NRT. If they still insist on leaving, then they must accept full responsibility for doing this and this must be documented in the patient records. Also record that you have offered NRT and advised the patient of the policy.

3.3 Human Resources

- 3.3.1 Human Resources will provide advice and assistance on the implementation of the policy; Advise on the appropriateness and support of the Trust's disciplinary procedure; Ensure job advertisements include reference to the smoke free policy, indicating adherence to it is contractual; Ensure appropriate reference to the smoke free policy is made during Induction training. The trust will require all new staff to undertake the NCSCT online very brief advice training http://elearning.ncsct.co.uk/vba-stage_1
- 3.3.2 The Trust will Require relevant staff to undertake the NCSCT online practitioner levels 1 & 2 training, followed by additional training for staff whose role will include supporting people who want to stop smoking. http://elearning.ncsct.co.uk/practitioner_training-registration

3.4 Occupational Health Service

- 3.4.1 The Occupational Health Service will provide advice on smoking cessation support available and provide literature for staff who wish to stop smoking; Review and provide additional support for staff who are undertaking smoking cessation programmes when required; Actively promote the benefits of not smoking.

3.5 Staff Side Organisation

- 3.5.1 The Staff Side Organisation will advise their members of their rights and responsibilities with regard to the policy.

4. Definitions

- 4.1 Smoking in enclosed, or substantially enclosed, public places has been banned since July 2007 (section 7, Heath Act 2006 and associated regulations). The ban includes manufactured and hand rolled cigarettes, pipes (including shisha and hookah water pipes), cigars and herbal cigarettes. The definition of smoking under the Act refers to tobacco and other substances in a lit form which are capable of being smoked.

5. What is our Policy?

- 5.1 There will be no smoking, including e-cigarettes and vapourisers in any buildings, grounds, rented, leased, sub-let or used by ULHT. Smoking inside cars whilst parked on Trust property is prohibited. Smoking will not be permitted within ULHT pool cars and vehicles.
- 5.2 Smoke free means that smoking, is not permitted anywhere within hospital buildings or

grounds. The use of E-Cigarettes, will be confined to clearly identified designated external areas in the Trust grounds.

- 5.3 The use of E-Cigarettes or Vaporises is not permitted inside any building or structure on the Trust sites.
- 5.4 The charging of any E-Cigarettes or Vaporises devices is prohibited in the Trust
- 5.5 This policy applies to all staff, patients, visitors, contractors and other person(s) who access any Trust site or enter any building that is owned, or used by the organisation for any purpose whatsoever.

6. Delivering the Policy

- 6.1 Our expectation is to promote and develop a culture across the Trust, Trust property and sites that smoking is unacceptable and that this is respected by patients, visitors, staff and contractors.
- 6.2 We aim to achieve a smoke free Trust by a change in culture and behaviours. This culture change will be achieved if we stay committed to a Smoke free Trust becoming a reality and respond to situations when this does not happen, and we see a breach as an opportunity rather than a failure of the policy.
- 6.3 Tobacco sales are not permitted on any NHS establishment. Advertising or promotion of tobacco products or companies is not permitted on any NHS establishment or in any of its publications. It is illegal to purchase tobacco products (cigarettes, tobacco, cigars) under the age of 18 years
- 6.4 E-Cigarettes or Vaporises devices may be purchased at the retail outlets on Trust sites It is at the discretion of the retailer to offer these devices for sale.
- 6.5 All main entrances to NHS sites and buildings on site are to be clearly signed to indicate that smoking is prohibited in both buildings and grounds. All pool vehicles are to display a no smoking sign within the vehicle.
- 6.6 The use of CCTV will take place and may be used to support compliance in conjunction with datix entries to record any incidents.
- 6.7 Elective patients and outpatients will be informed of the policy prior to attending their hospital appointment. Support through nursing staff and smoking cessation specialists will be provided if this is requested. Non elective/emergency admission patients will be advised of the policy upon admission.
- 6.8 The Disciplinary policy will be invoked as appropriate where members of staff contravene the policy.

- 6.9 The Trust do not want anyone to feel that they need to engage in difficult or challenging situations and should not approach individuals (whether staff or patients) to ask them to stop smoking unless they are confident and feel that it is safe to do so.
- 6.10 Should any ULHT staff member have a complaint made against them for politely pointing out the policy to anyone who is smoking, they will have the Trust's full support for taking such action, which will be in compliance with this policy.

7. E-Cigarettes

- 7.1 The use of E-Cigarettes, is not permitted in Trust buildings and premises it is only permitted in clearly identified/designated areas on trust sites/grounds
- 7.2 E-cigarettes are battery-powered products that release a visible vapour that contains liquid nicotine that is inhaled by the user. Currently, e-cigarettes fall outside the scope of smoke-free legislation.
- 7.3 There is evidence that e-cigarettes may help some smokers to give up, but there is a lack of evidence on the health risks that they pose to the individual using them and those in close proximity. In relation to the risk to the user, there is a lack of quality control because the manufacture and sale of e-cigarettes is not tightly regulated and e-cigarettes contain nicotine, which is addictive. In relation to the risk to third parties, the trust believes that work colleagues could be exposed to e-cigarette vapours.
- 7.4 The Trust is also concerned that the use of e-cigarettes might undermine existing restrictions on smoking in workplaces, particularly in a healthcare setting, by misleading people to believe it is acceptable to smoke.
- 7.5 The Trust fully recognises the significance to the individual of substituting normal tobacco products for E cigarettes as a commitment towards stopping smoking.
- 7.6 These devices are not yet regulated and therefore cannot be recommended or dispensed by healthcare professionals. Staff will be able to offer support and access to regulated treatments to help individuals quit smoking.
- 7.7 In addition, e-cigarettes present a known fire-risk recent events have highlighted potential dangers such as the chargers and integral batteries being fire hazards especially in health care settings where there may be oxygen enriched atmospheres.

8. Implementation, Monitoring and Review

- 8.1 The policy will be subject to review through the Trust's Procedural process for documents to be reviewed by the Author prior to the Policy Approval Group every two years if appropriate in response to exceptional circumstances or relevant changes in legislation or guidance.
- 8.2 Various strategies will be used to raise awareness of this policy and responsibilities under this policy.
- Manager Briefings
 - Information on Newsline
 - HR News for Managers
 - HR Policies on the intranet page
 - Signage via facilities
 - Elective patients and outpatients invite letters informing individuals of ULHT's policy.
 - Conflict resolution training.

Monitoring Compliance

| Minimum requirement to be monitored –monitoring against standards set out in policy | Process for monitoring e.g. audit | Responsible individuals/ group/ committee | Frequency of monitoring/ audit/ reporting | Responsible individuals/ group/ committee for review of results and determining actions required |
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Appendix 1 - Support for Smokers

STEP 1: Identification of smokers

The first step in treating tobacco dependence is to identify current tobacco users.

Ask every patient if they currently smoke tobacco. **Record** smoking status in Current Physical Health Assessment.

The identification and recording of each patient's smoking status needs to be completed regularly, i.e. on admission and discharge from hospital.

STEP 2: Advise and offer support

To comply with the Trust's Smoke free Policy and the NICE guidelines for smoking cessation in secondary care smokers will need to abstain from smoking whilst in Trust buildings and grounds during an inpatient admission.

Making an attempt to permanently stop smoking is an opportunity not an obligation. During an inpatient admission a smoker has **three** options

OPTION 1: to temporarily abstain from smoking whilst in buildings and in the grounds, **with** pharmacological and/or psychological support

OPTION 2: to temporarily abstain from smoking whilst in buildings and in the grounds, **without** pharmacological and/or psychological support

OPTION 3: to use the opportunity to make a sustained quit attempt, with pharmacological and/or psychological support

Regardless of which option the patient chooses, **every smoker** should be **offered NRT** to manage their tobacco dependence **within a reasonable time on** arrival to an inpatient unit. This should be followed up by the offer of tobacco dependence treatment support from stop smoking advisory service.

Offering support to quit or manage tobacco withdrawal symptoms during a period of temporary abstinence, rather than asking a smoker how interested are they in stopping or telling a person they should stop, leads to more people making a quit attempt.

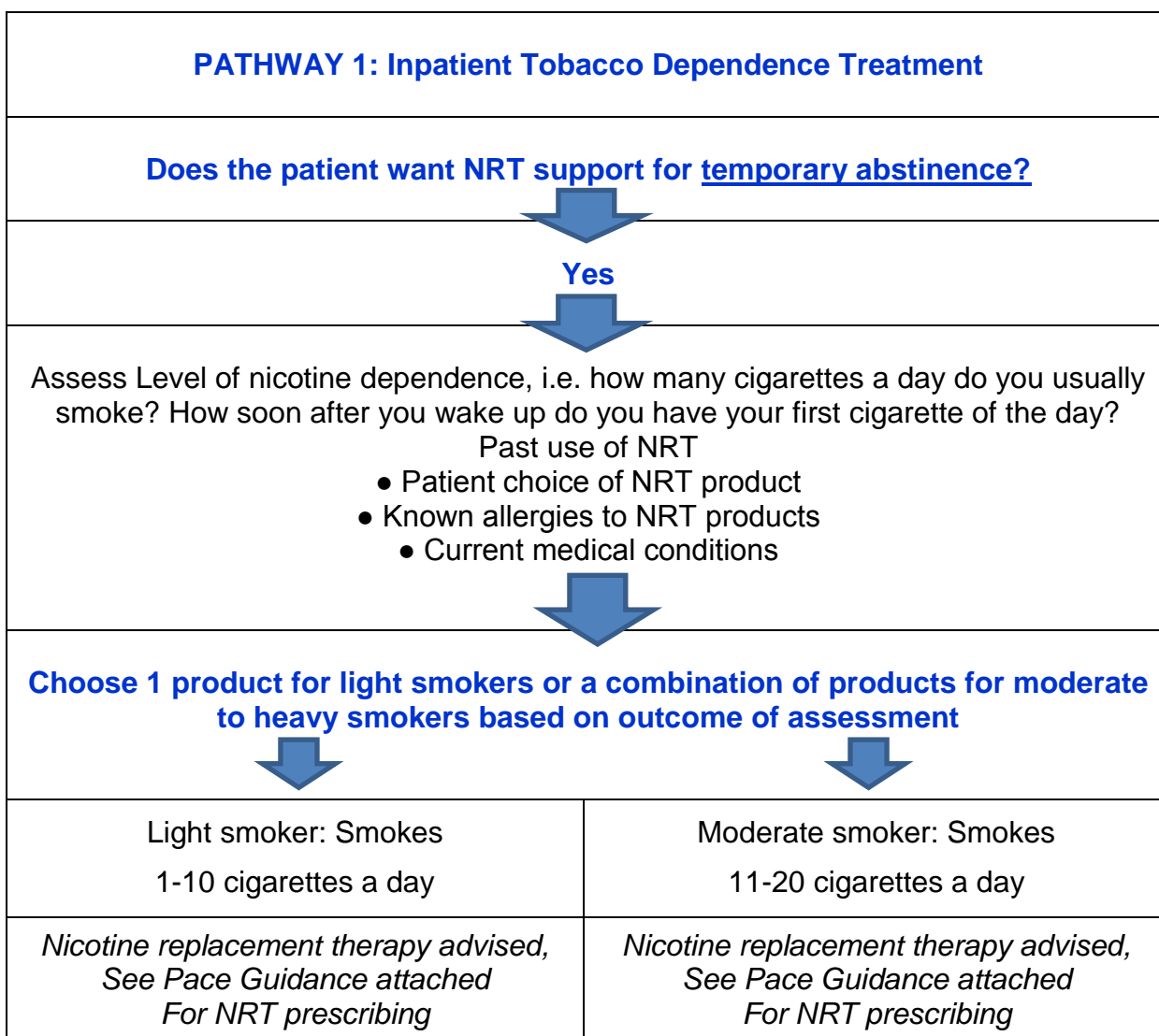
The most effective method of quitting or managing tobacco withdrawal symptoms during a period of temporary abstinence, is with combination NRT (i.e. a patch and oral product) and behavioural support. Advising the smoker that stopping smoking is one of the best things they can do for their health and wellbeing is recommended by the Department of Health.

Record in the Current Physical Health Assessment /Patient Record.

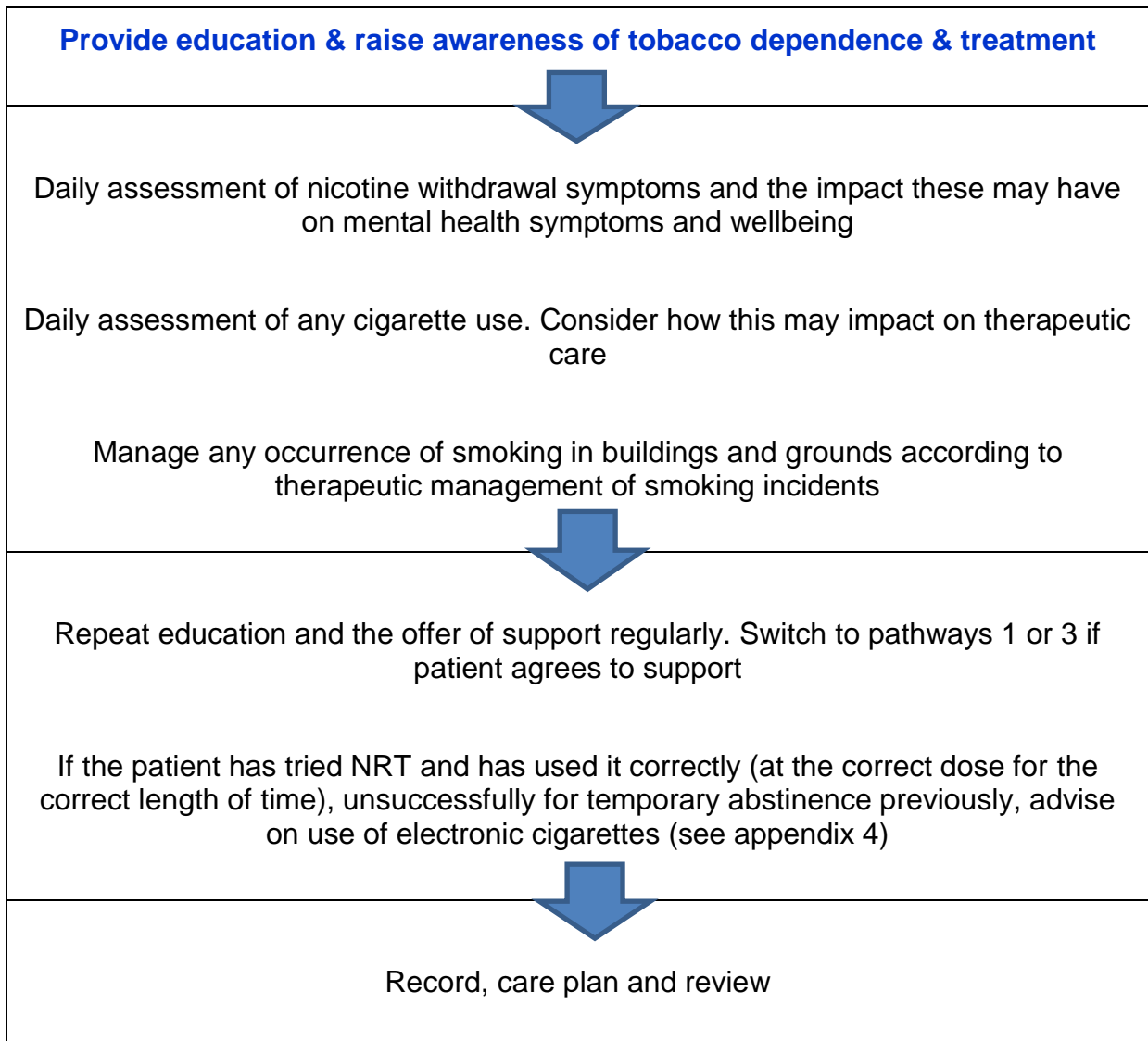
1. That you have advised the smoker that stopping smoking is one of the best things they can do for their health and wellbeing
2. If the smoker wants NRT for temporary abstinence
3. If they want to see a tobacco dependence treatment advisor during their admission

STEP 3: Act on smoker’s response

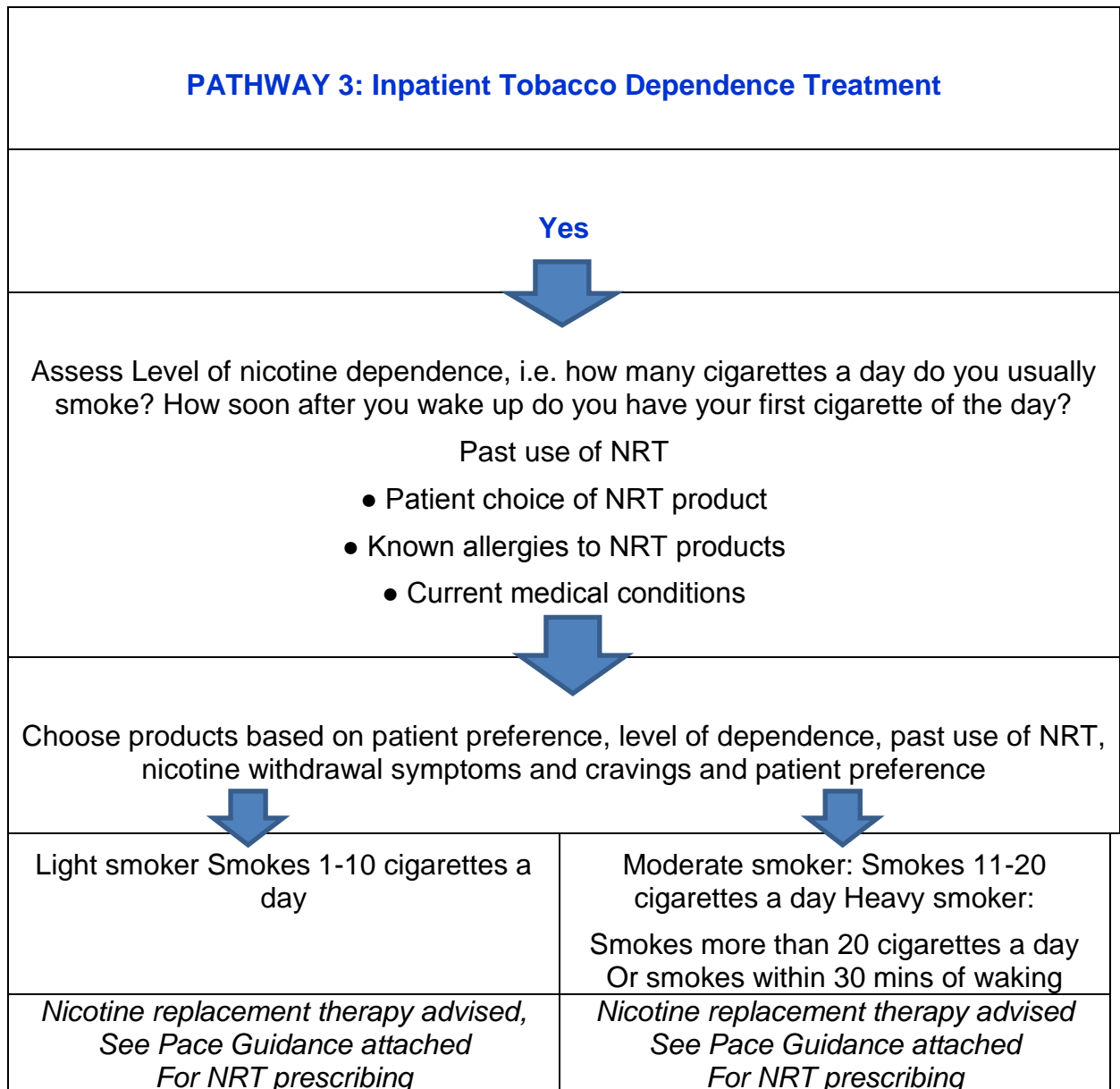
For smokers choosing **Option 1**: to temporarily abstain from smoking whilst in buildings and in the grounds, **with** pharmacological and/or psychological support, **follow treatment pathway 1** below.



For smokers choosing **OPTION 2**: to temporarily abstain from smoking whilst in buildings and in the grounds, **without** pharmacological and/or psychological support, **follow treatment pathway 2** below



For smokers choosing **OPTION 3**: to use the opportunity to make a sustained quit attempt, with pharmacological and/or psychological support, follow treatment pathway 3 below



Appendix 2 – ULHT Patients

ULHT Patients What does this mean for you

Questions and Answers

Introduction

Welcome to United Lincolnshire Hospitals NHS Trust a smoke free organisation.

Being smoke free means that patients, carers, staff and other visitors will not be allowed to smoke on any ULHT premises. This includes our buildings and grounds, as well as vehicles within those grounds. Anyone wishing to smoke will need to leave Trust premises.

Support will be provided for patients in our care to help them either abstains from smoking during their stay or to try and stop smoking permanently

Why smoke free?

The purpose of the smoke free policy is to protect and improve the health and wellbeing of all employees, visitors, contractors but most importantly you the patient.

Completely smoke free

Hospitals and grounds create a clean, pleasant environment for people trying to stop smoking and reduces triggers that cause many smokers to relapse. Smoking increases a patient's risk of complications and often delays their recovery.

If smoking occurs at entrances and windows, the smoke will drift in through the doors and windows and pose a further hazard to the health and wellbeing of inpatients.

Stop Smoking support for patients

If you have a planned intervention in hospital, stopping smoking weeks or even months before your procedure will really help your recovery. Time in hospital is a great time to stop smoking and research tells us that hospitalised patients are more successful at stopping than any other smokers.

Our staff are here to help and support you throughout both your hospital stay and when you go home. On admission, all patients, who smoke, will be prescribed Nicotine Replacement Therapy (NRT) and with their consent will be referred to our Smoke free Service.

What will happen if I don't comply?

Patients will be given every support to comply with the smoke free policy and prescribed NRT products to ease withdrawal symptoms during their stay in hospital.

Anyone smoking on site will be asked to stop smoking and extinguish their cigarette.

All staff are expected to remind patients and their visitors of the smoke free policy.

How will you ensure that people don't smoke on ULHT premises?

Prior to planned admissions to hospital, patients will be advised that ULHT is smoke free and consequently smoking is not permitted in the hospital or grounds. An individual's smoking status will be logged in their clinical records so they will be offered support to either temporarily refrain from smoking or to attempt to quit. This support will include nicotine replacement therapy (NRT) alongside behavioural and psychological. Patients and carers will be asked not to bring tobacco, cigarettes, lighters or matches with them to hospital.

For unplanned admissions, patients will not be allowed to keep tobacco, cigarettes, lighters or matches with them. If the patient arrives with a carer or relative, they will be asked to take the prohibited items home. If the patient is unaccompanied, our staff will store the items for them until they are discharged.

The level of support provided to patients who are abstaining from smoking will be constantly monitored as part of that individual's package of care.

We want to develop a culture where smoking is viewed as unacceptable across our sites, and for this to be respected. In situations where an individual is breaching the smoke-free policy, that person may be approached by a member of staff who will remind them of our smoke-free status and signpost them to the appropriate smoking cessation support.

Can ULHT legally enforce being smoke free? What about my human rights?

In July 2007, the government introduced legislation in England banning smoking in workplaces and enclosed public spaces, and ULHT's decision to go smoke-free is covered by that legislation. In addition, National Institute for Health and Care Excellence (NICE 2013) guidance recommends that smoking is banned on hospital sites.

After Rampton Hospital in Nottinghamshire went smoke-free, the argument about infringement of a service user's human rights was legally tested in the Court of Appeal in 2008. The court ruled that a hospital is not the same as a home environment and should support the promotion of health and wellbeing. Patients can therefore legally be prevented from smoking for health and security reasons.

What support will there be for patients who smoke?

Denying a smoker a nicotine substitute is not acceptable so clearly it is very important that the appropriate support is in place to enable smokers to abstain from smoking while on our premises.

Department of Health guidance recommends a combination of intensive behavioural and psychological support alongside medication to minimise nicotine withdrawal symptoms and help with cravings.

Following assessment, smokers will be offered nicotine replacement therapy (NRT) and behavioural support. Those who wish to use the opportunity of a hospital stay to try and give up smoking will be referred to a trained stop smoking advisor.

What about electronic cigarettes?

At present electronic cigarettes and all forms of vaping are not regulated and therefore we cannot recommend their use. Patients should not use E cigarettes and Vapes on hospital grounds. E cigarette's and Vape chargers should not be used as they constitute a fire risk

Appendix 3 – ULHT Staff

ULHT Staff What does this mean for you

Questions and Answers

What about patients who need to smoke?

Nothing harmful will happen to someone if they don't smoke. They may experience withdrawal symptoms due to lack of nicotine, but this can be easily managed with nicotine replacement therapy (NRT). Patients in the Emergency department and Inpatients should be offered NRT during their stay and a referral to the stop smoking service. Outpatients can be directed to the Lloyds pharmacy where they can purchase NRT.

What if the patient asks to leave the ward to smoke?

Remind the patient of the smoke free policy and make sure they have been offered NRT. If they still insist on leaving, then they must accept full responsibility for doing this and this must be documented in the patient records. Also record that you have offered NRT and advised the patient of the policy.

What if a patient or visitor gets really aggressive when I ask them not to smoke?

If someone gets really aggressive or violent, the standard NHS procedures for aggressive behaviour should be invoked. A 'zero tolerance' policy applies in the NHS in all other aspects of treatment and smoking is not an exception. Security should be contacted on extension 3333 if staff feel in any danger.

What if people just carry on smoking?

We anticipate that not everyone will stop smoking when we ask them to and that there are limits to what we can do. Politely provide people with information about the smoke free policy, point to the signage .

What if a patient asks, "where can I go to smoke?"

It is important to reiterate they cannot smoke anywhere on the site. It is important that we don't tell them where they can smoke as this would condone smoking.

What should I advise patients to do, if they are craving a cigarette?

Find out if they have been offered NRT and if not, advise them to ask the nurse to get it prescribed. NRT can be used by smokers for temporary abstinence as well as for people wanting to quit for good.

What about electronic cigarettes?

At present electronic cigarettes and all forms of vaping are not regulated and therefore we cannot recommend their use. Patients should not use E cigarettes and Vapes on hospital grounds. E cigarette's and Vape chargers should not be used as they constitute a fire risk.

How should people be approached if they continue to smoke?

Anyone seen smoking on site should be politely asked not to smoke. Staff are expected to remind people of the smoke free policy whilst avoiding putting themselves at risk. A suggested script might be: " Excuse me can I remind you that this is a smoke free site and you can't smoke here".

Approaching a group of smokers - " I'm sorry folks, would it be ok for you not to smoke until you are off the hospital grounds?"

Inpatients - " Hello, my name is.....I'm wondering if anyone on the ward has offered you things like nicotine patches to help with your smoking? I am afraid you cannot smoke here. You can just ask the nurse for nicotine replacement when you get back to the ward".

If they are close to signage it is easy to point to it to reinforce the message. Business cards with information about where to get support will be made available to all staff to hand out.

In the event visitors refuse to extinguish their cigarettes, please contact security on 3333

What about at night- especially in A&E and Emergency Admissions Areas

Nicotine Replacement Therapy will be available as stock in A&E. Patients can be offered this (as long as there are no clinical contraindications), especially if they are becoming agitated from missing their cigarettes. (Agitation is a common sign of nicotine withdrawal)

What if someone has just had bad news/bereaved and is smoking?

If someone is obviously distressed and smoking, a sensitive approach should be taken. " Hello, my name is.....I am sorry you are having a difficult time. Would it be ok for you not to smoke in the hospital?"

Who is going to enforce all of this?

This is everyone's responsibility. For this to succeed everyone needs to be prepared to remind smokers of our policy. Business cards will be made available on wards and main reception areas for you to have in your pocket- so as a minimum you could hand these out to smokers.

Staff are expected to remind people of the smoke free policy and only approach people if they feel comfortable to do so and avoiding putting themselves at risk.

Appendix 4 – Management of ULHT Staff

Management of ULHT Staff/Employees

Will staff smoking breaks be allowed?

Staff will be encouraged to take their official breaks. As smoking will not be permitted on the grounds, we would encourage smokers to take their break and use nicotine replacement therapy like the inhalator to help cope with cravings.

What about staff who want to smoke at night- we are worried about their safety if they go off site?.

It is important that night staff take their official breaks. We would encourage staff who smoke to first consider using alternatives, like the nicotine replacement therapy inhalator instead of tobacco during their shift.

There is a clear disciplinary procedure for staff who do not follow hospital regulations and contractual obligations. This will apply to all levels of staff.

So where can I go to smoke?

As a member of staff you cannot smoke in uniform or with a hospital ID badge whether on or off duty. You should not smoke at hospital entrance and exits. Trust employees are not entitled to take breaks during working hours for the purpose of smoking. If you wish to smoke in your official break you will need to leave the premises and change out of uniform. We would encourage you to walk whilst smoking to avoid groups of smokers congregating in residential areas.

What if staff just carry on smoking?

Politely provide staff with information about the smoke free policy, point to the signage .If staff carry on smoking this is a disciplinary matter which should be escalated to their manager.

There is a clear disciplinary procedure for staff who do not follow hospital regulations and contractual obligations. This will apply to all levels of staff

Appendix 5 – GUIDANCE ON THE PRESCRIBING OF SMOKING CESSATION THERAPY



Greater East Midlands Commissioning Support Unit in association with Lincolnshire Clinical Commissioning Groups, Lincolnshire Community Health Services, United Lincolnshire Hospitals Trust and Lincolnshire Partnership Foundation Trust

Lincolnshire Prescribing and Clinical Effectiveness Bulletin

Volume 8; Number 17

October 2014

GUIDANCE ON THE PRESCRIBING OF SMOKING CESSATION THERAPY

- Smoking cessation services are most effective if patients are offered a combination of behavioural support and pharmacotherapy.
- To ensure the most effective use of NHS resources, patients requiring pharmacotherapy to support smoking cessation should be referred into a smoking cessation service (i.e. Phoenix Smoking Cessation Service).
- Nicotine Replacement Therapy (NRT), varenicline or bupropion should only be prescribed as part of a smoking cessation programme where a smoker makes a commitment to stop smoking and sets a stop date.
- Initial therapy should only be prescribed to last until two weeks after the stop date; at this point the patient needs to be reviewed to ensure that the quit attempt is still ongoing.
- Individuals should only receive a maximum of 12 weeks pharmacotherapy related to any one quit attempt. If further supplies are required to prevent the occurrence of craving, individuals should be advised to purchase these themselves. There may be a minority of patients on varenicline that require an additional 12 week course to reduce the risk of relapse.
 - A gap of 3 months from the last appointment (12 weeks) should be maintained between repeated quit attempts for the majority of smokers. This will ensure that individuals are sufficiently motivated prior to setting another quit date and will avoid the risk of continuous repeat prescribing of NRT where success may be severely limited. In exceptional circumstances, particularly where the quit attempt is interrupted by a traumatic event, the individual may reset their quit date and continue with pharmacotherapy for an extended period.
 - Nicotine replacement therapies (NRT) should not be prescribed for individuals who wish to reduce the amount they smoke but have not agreed to stop smoking, as this level of support is not currently commissioned in Lincolnshire
 - A successful quit attempt is dependent upon the individual being sufficiently motivated and compliant with therapy. To maximize engagement, patient choice should be taken into account, subject to contraindications and potential for adverse reactions. National guidance does not recommend one form of pharmacotherapy in preference to another; local figures suggest that higher quit rates are obtained with varenicline.
 - Despite the evidence that varenicline is associated with superior long-term quit rates, the wide range of adverse effects, cautions and contra-indications associated with this form of pharmacotherapy mean that it can only be initiated following full consideration of risks and benefits by the patient's GP. Varenicline tablets 500microgram and 1mg are on the *Lincolnshire Joint Formulary*; designation GREEN.
 - Evidence suggests that bupropion therapy does not achieve quit

rates as high as those achieved by NRT or varenicline. Nonetheless, the product retains a third line role and may be particularly useful in ex-smokers relapsing after a prolonged period who have previously used this product to support a successful quit attempt. Bupropion sustained release tablets 150mg (*Zyban*)

remain on the *Lincolnshire Joint Formulary* as a third line choice; designation GREEN.

- Neither bupropion nor varenicline should be used concurrently with nicotine replacement therapies.
- The majority of people requiring NRT as part of a smoking cessation programme should be prescribed a long-acting transdermal patch in combination with an immediate release, short-acting product to counteract cravings. Where short-acting NRT products are prescribed as monotherapy, the maximum dose for each product is as stated in the *BNF* and product SPC. When a short-acting NRT product is used in combination with a long-acting nicotine transdermal patch, the maximum dose of the short acting product should be reduced to half the stated maximum dose. Combination NRT prescribing should never involve more than two formulations, one long-acting and one short-acting.
- Transdermal nicotine patches are an effective way of delivering background continuous nicotine replacement therapy. For the majority of patients, a 16 hour patch is preferred with the starting dose based on the individual's previous smoking habit. A 24 hour patch is indicated for those smokers usually requiring their first cigarette within a few minutes of waking and for shift workers with unpredictable work patterns. The available patches are comparably priced. Due to the preference for a 16 hour patch, the *Nicorette Invisipatch* (all strengths) is approved for inclusion in the *Lincolnshire Joint Formulary* designation GREEN. The *NiQuitin* range of patches (all strengths) offer 24 hour cover and are also approved for *Formulary* inclusion; designation GREEN. *Nicotinell* patches are classed as non-formulary and should not be prescribed.
- If nicotine chewing gums are prescribed, mint flavours are often more palatable and are better tolerated by most people. *Nicorette* icy white flavour gum is advocated as the first line product of choice and is approved for inclusion in the *Lincolnshire Joint Formulary*; designation GREEN.
- *NiQuitin Lozenge* 2mg and 4mg and *NiQuitin Minis Lozenges* 1.5mg and 4mg are advocated first line where a short-acting lozenge is indicated. Both formulations are approved for inclusion in the *Lincolnshire Joint Formulary* and designated GREEN. *NiQuitin* orodispersible film 2.5mg has already been evaluated by PACEF and designated RED-RED. It is not approved for use through the *Joint Formulary* and should not be prescribed. Due to current supply problems with *NiQuitin Minis*, *Nicorette Cools* 2mg and 4mg are also designated GREEN and included in the *Lincolnshire Joint Formulary*.
- Nicotine oral sprays, nasal sprays and inhalators are relatively high cost in comparison with other formulations of NRT. *Nicorette QuickMist* oromucosal spray and *Nicorette Inhalator* are approved for use through the *Lincolnshire Joint Formulary* and are designated GREEN; they should only be prescribed for those who have previously failed to quit using other forms of NRT. *Nicorette Nasal Spray* is not approved for inclusion in the *Joint Formulary* and should not be prescribed.
- Electronic cigarettes are currently not classed as medicines and therefore do not have to comply with the same regulatory standards as licensed nicotine replacement therapies. There are reports that the quality and nicotine content of these products varies widely between brands. There is only limited evidence of effectiveness in supporting a smoking cessation attempt, although some patients are being supported to stop smoking using electronic cigarettes through the Phoenix service. However, in most cases, where the person wants to stop smoking, evidence based pharmacotherapy using licensed NRT products, varenicline or bupropion is preferred.

FORMULARY OF SMOKING CESSATION PRODUCTS

| Drug | Indication(s) | Traffic Light and Joint Formulary Status |
|---|---|---|
| First line: <i>Short-acting nicotine formulations</i> | | |
| Nicotine chewing gum (<i>Nicorette Gum</i>) icy white flavour 2mg and 4mg | Nicotine replacement as an aid to smoking cessation or reduction. | GREEN Possible first line choice of short-acting therapy. Included in the <i>Lincolnshire Joint Formulary</i> . |
| Nicotine lozenge (<i>NiQuitin Lozenge</i>) 2mg and 4mg | Nicotine replacement as an aid to smoking cessation or reduction. | GREEN Possible first line choice of short-acting therapy. Included in the <i>Lincolnshire Joint Formulary</i> . |
| Nicotine lozenge (<i>NiQuitin Minis Lozenges</i>) 1.5mg and 4mg | Nicotine replacement as an aid to smoking cessation or reduction. | GREEN Possible first line choice of short-acting therapy. Included in the <i>Lincolnshire Joint Formulary</i> . |
| Nicotine lozenge (<i>Nicorette Cools</i>) 2mg and 4mg | Nicotine replacement as an aid to smoking cessation or reduction. | GREEN Possible first line choice of short-acting therapy. Included in the <i>Lincolnshire Joint Formulary</i> due to current supply problems with <i>NiQuitin Minis</i> .. |
| First line: <i>Long-acting transdermal nicotine formulations</i> | | |
| Nicotine transdermal patch 10mg, 15mg and 25mg(16 hours) (<i>Nicorette Invisipatch</i>) | Nicotine replacement as an aid to smoking cessation or reduction. | GREEN Possible first line choice of long-acting therapy. For the majority of patients, a 16 hour patch is preferred with the starting dose based on the individual's previous smoking habit. Included in the <i>Lincolnshire Joint Formulary</i> |
| Nicotine transdermal patch 7mg, 14mg, 21mg (24 hours) (<i>NiQuitin</i>) | Nicotine replacement as an aid to smoking cessation or reduction. | GREEN Possible first line choice. A 24 hour patch is indicated for those smokers usually requiring their first cigarette within a few minutes of waking and for shift workers with unpredictable work patterns. Included in the <i>Lincolnshire Joint Formulary</i> |
| Second line: <i>Short-acting nicotine formulations</i> | | |
| Nicotine inhalation cartridge plus mouthpiece (<i>Nicorette Inhalator</i>) 15mg | Nicotine replacement as an aid to smoking cessation or reduction. | GREEN Possible second line choice of short-acting therapy. Included in the <i>Lincolnshire Joint Formulary</i> . |
| Nicotine oromucosal spray (<i>Nicorette QuickMist</i>) 1mg per dose | Nicotine replacement as an aid to smoking cessation | GREEN Possible second line choice of short-acting therapy. Included in the <i>Lincolnshire Joint Formulary</i> . |
| Others | | |
| Bupropion 150mg sustained release tablets (<i>Zyban</i>) | Aid to smoking cessation | GREEN 3 rd line choice Included in the <i>Lincolnshire Joint Formulary</i> |
| Varenicline 500microgram/1mg tablets (<i>Champix</i>) | Smoking cessation | GREEN Possible first line choice. Included in the <i>Lincolnshire Joint Formulary</i> |

Products not listed on this Formulary are not recommended for use and should not be prescribed.

Introduction

General guidance

National Institute for Clinical Excellence (NICE) *Quality Standard 43 - Smoking cessation: supporting people to stop smoking* (August 2013)

NICE emphasize the importance of:

- (1) healthcare practitioners proactively asking patients if they smoke and offering identified smokers advice on how to stop.
- (2) offering smokers who wish to stop a referral to an evidence-based smoking cessation service.
- (3) ensuring that people being supported to stop by an evidence-based smoking cessation service are offered both behavioural support and pharmacotherapy in combination as this approach has the highest likelihood of success.
- (4) ensuring that people being supported to stop smoking are offered a full course of pharmacotherapy.
- (5) ensuring that people being supported to stop smoking set a quit date and are assessed for carbon monoxide levels 4 weeks after that date.

Guidance on the use of nicotine replacement therapy to reduce but not stop smoking

NICE Public Health Guidance 45 - *Tobacco: harm-reduction approaches to smoking* (June 2013)

This PHG acknowledges that people:

- may not be able (or may not want) to stop smoking in one step.
- may want to stop smoking without necessarily giving up nicotine.
- may not be ready to stop smoking, but may want to reduce the amount they smoke.

PACEF Recommendations

(1) Smoking cessation services are most effective if patients are offered a combination of behavioural support and pharmacotherapy. This was backed up by local figures published by Lincolnshire Community Health Services in May 2014.

(2) To ensure the most effective use of NHS resources, patients requiring pharmacotherapy to support smoking cessation should be referred into a smoking cessation service.

(3) Lincolnshire County Council has confirmed that NICE PHG 45 is currently not commissioned within Lincolnshire. As a result of this,

Guidance on the appropriate interval between treatment episodes

NICE Public Health Guidance 10 - *Smoking cessation services in primary care, pharmacies, local authorities and workplaces, particularly for manual working groups, pregnant women and hard to reach communities* (February 2008)

NICE recommendations state that:

- Following an unsuccessful quit attempt using NRT, varenicline or bupropion, a subsequent quit attempt should not be supported within 6 months unless special circumstances have hampered the person's initial attempt to stop smoking, when it may be reasonable to try again sooner.
- It may take many attempts before a person can successfully quit smoking and encouragement needs to be maintained throughout.

Department of Health - *Local Stop Smoking Services - Key updates to the 2011/12 service delivery and monitoring guidance for 2012/13*

This is a good practice guide for the provision of smoking cessation services and provides some guidance on the recommended interval between treatment episodes:

- When a client has not managed to stop smoking, there is no definitive period of time required between the end of a treatment episode and the start of another. The stop smoking adviser should use discretion and professional judgement when considering whether a client is ready to receive support to immediately attempt to stop again. If this is the case, the client must start a new treatment episode, attend one session of a structured multi-session intervention, consent to treatment and set a quit date with a stop-smoking adviser.

PACEF Recommendations

(4) Following discussion between representatives from the Phoenix Smoking Cessation Service and Lincolnshire Public Health it is recommended that a gap of 3 months from the last appointment (12 weeks) should be maintained between repeated quit attempts for the majority of smokers. This will ensure that individuals are sufficiently motivated prior to setting another quit date and will avoid the risk of continuous repeat prescribing of NRT where success may be severely limited.

Pharmacotherapy

NICE Public Health Guidance 10 - *Smoking cessation services in primary care, pharmacies, local authorities and workplaces, particularly for manual working groups, pregnant women and hard to reach communities* (February 2008)

The main recommendations relating to the use of pharmacotherapy are as follows:

- Offer NRT, varenicline or bupropion, as appropriate, to people who are planning to stop smoking.
- Before prescribing a treatment take into account the person's intention and motivation to quit and how likely it is they will follow the course of treatment. Consideration should be given to which treatments the individual prefers, whether they have attempted to stop before (and how), and if there are medical reasons why they should not be prescribed particular pharmacotherapies.
- Offer advice, encouragement and support, including referral to the NHS Stop Smoking Service, to help people in their attempt to quit.
- NRT, varenicline or bupropion should normally be prescribed as part of an abstinence-contingent treatment, in which the smoker makes a commitment to

stop smoking on or before a particular date (target stop date). The prescription of NRT, varenicline or bupropion should be sufficient to last only until 2 weeks after the target stop date. Normally, this will be after 2 weeks of NRT therapy, and 3–4 weeks for varenicline and bupropion, to allow for the different methods of administration and mode of action. Subsequent prescriptions should be given only to people who have demonstrated, on re- assessment that their quit attempt is continuing.

PACEF Recommendation

(5)A successful quit attempt is dependent upon the individual being sufficiently motivated and compliant with therapy. To maximize engagement, patient choice should be taken into account, subject to contraindications and potential for adverse reactions. National guidance does not recommend one form of pharmacotherapy in

Duration of treatment

The recommended duration of treatment for each form of pharmacotherapy is tabulated below:

| | Maximum length of treatment |
|--------------------------------|--|
| Nicotine Replacement Therapy | 12 weeks |
| Bupropion (<i>Zyban</i>) | 7 to 9 weeks |
| Varenicline (<i>Champix</i>) | 12 weeks (but can be repeated in abstinent individuals to reduce risk of relapse). |

PACEF Recommendation

(6)In accordance with guidance from Phoenix Smoking Cessation Service and Lincolnshire Public Health, it is recommended that individuals should only receive a maximum of 12 weeks pharmacotherapy related to any one quit attempt. If further supplies are required to prevent the occurrence of craving, individuals should be advised to purchase these themselves. There may be a minority of patients on varenicline that require an additional 12 week course to reduce the risk of relapse.

Choice of therapy

The table below illustrates that NRT (in a variety of formulations) and varenicline are widely prescribed in all four Lincolnshire Clinical Commissioning Groups (CCGs): in comparison, bupropion is prescribed very infrequently. NRT is most commonly prescribed in a patch formulation:

| Product | LECCG Items | LWCCG Items | SLCCG Items | SWLCCG Items |
|---|--------------------|--------------------|--------------------|---------------------|
| Bupropion 150mg SR tablets (<i>Zyban</i>) | 21 | 26 | 13 | 22 |
| Varenicline 500microgram/1mg tablets (<i>Champix</i>) | 1,575 | 1,009 | 731 | 591 |
| NRT | | | | |
| NRT patches | 1281 | 1094 | 583 | 474 |
| NRT chewing gum | 164 | 129 | 111 | 71 |
| NRT lozenges/tablets/strips | 364 | 270 | 154 | 107 |

| | | | | |
|---------------------|-----|-----|-----|-----|
| NRT sprays | 289 | 222 | 101 | 82 |
| Nicorette inhalator | 512 | 377 | 220 | 185 |

Figures derived from CCG prescribing data for the 4th quarter of 2013/14

Varenicline (*Champix*)

Varenicline is a selective nicotine receptor partial agonist used as an aid for smoking cessation. Clinical evidence published as part of NICE Technology Appraisal 123 supports claims that varenicline is more effective than NRT in terms of long term quit rates. Local data from the LCHS smoking cessation report published in May 2014 also supports this conclusion.

Varenicline (*Champix*) is only licensed for use in adults aged over 18. Treatment should usually be initiated 1-2 weeks prior to the target stop date, with an initial dose of 500mcg once daily for three days increasing to 500mcg twice daily for 4 days; the usual maintenance dose is 1mg twice daily for 11 weeks, leading to 12 weeks treatment in total. The maintenance dose can be reduced to 1mg twice daily if not tolerated. Sometimes, Phoenix recommends tapering of varenicline dosage towards the end of the 12 weeks. As stated above, the 12 week course can be repeated in abstinent individuals to reduce the risk of relapse, although this goes beyond the 12 week programme of support that Phoenix is commissioned to provide.

Varenicline is associated with a wide range of adverse effects, most commonly gastrointestinal disturbances, appetite changes, dry mouth, taste disturbance, headache, drowsiness, dizziness, sleep disorders and abnormal dreams. It is contraindicated in pregnancy and when breast feeding. In 2008, the MHRA issued a safety alert highlighting a potential association between varenicline therapy and increased risk of suicidal thoughts and behaviour. Patients should be advised to stop treatment and contact their doctor immediately if they develop suicidal thoughts, agitation or depressed mood. Those with a history of psychiatric illness should be monitored closely while taking varenicline. Varenicline should also be used with caution in those with a history of cardiovascular disease and in those with a predisposition to seizures.

Decision making around the appropriateness of initiation of varenicline in an individual patient requires access to the individual patient record. As a result of this, the final decision as to whether varenicline treatment is clinically appropriate remains the responsibility of the clinician that prescribes the therapy.

PACEF Recommendation

(7)Despite the evidence that varenicline is associated with superior quit rates, the wide range of adverse effects, cautions and contra-indications associated with this form of pharmacotherapy mean that it can only be initiated following full consideration of risks and benefits by the patient's GP. Varenicline tablets 500microgram and 1mg remain on the *Lincolnshire Joint Formulary*; designation GREEN.

Bupropion hydrochloride (*Zyban*)

Bupropion (*Zyban*) has previously been used as an antidepressant. Its mode of action in smoking cessation is not clear and may involve an effect on noradrenaline and dopamine neurotransmission.

Bupropion (*Zyban*) is only licensed for use in adults aged over 18; it should only be

used in those smoking at least 15 cigarettes a day and weighing at least 45kg.

The dose of bupropion is 150mg initially once daily for 6 days then twice daily for a period of 7 to 9 weeks, commencing treatment 1 to 2 weeks before target stop date.

Bupropion is associated with a number of adverse effects including: dry mouth, gastrointestinal disturbances, taste disturbance, agitation, anxiety, dizziness, depression, headache, impaired concentration, insomnia, tremor, fever, pruritus, rash and sweating. It is contraindicated in those with severe hepatic cirrhosis, CNS tumour, history of seizures, eating disorders or bipolar disorder. It should be used with caution in the elderly and in those with a predisposition to seizures, those on concomitant drug therapy which lowers the seizure threshold, those with a history of alcohol abuse and those with a history of head trauma or diabetes.

PACEF Recommendation

(8)Evidence suggests that bupropion therapy does not achieve quit rates as high as those achieved by NRT or varenicline. Nonetheless, the product retains a third line role and may be particularly useful in ex-smokers relapsing after a prolonged period who have previously used this product to support a successful quit attempt. Bupropion sustained release tablets 150mg (Zyban) remain on the *Lincolnshire Joint Formulary* as a third line choice; designation GREEN.

Nicotine Replacement Therapy

There are several different types of formulation available:

- Patches – controlled release patches delivering a continuous dose of background nicotine over a 16 to 24 hour period.
- Oral products - chewing gum, lozenges, sublingual tablets, oral film strips, oral or nasal sprays – designed to provide a short-acting, additional dose of nicotine to relieve intense craving.
- Inhalator devices – provide an inhaled dose of nicotine; the device mimics the delivery system of a cigarette or e-cigarette.

Selection of NRT

NICE Public Health Guidance 10 - *Smoking cessation services in primary care, pharmacies, local authorities and workplaces, particularly for manual working groups, pregnant women and hard to reach communities* (February 2008)

- Consider offering a combination of a long-acting nicotine patch with a shorter acting form of NRT (e.g. gum, inhalator, lozenge or nasal spray) to people who show a high level of dependence on nicotine or who have found single forms of NRT inadequate in the past.
- Explain the risks and benefits of using NRT to young people aged from 12 to 17, women who are pregnant or breastfeeding and those with unstable cardiovascular disorders.
- To maximise the benefits of NRT, people should be strongly encouraged to use behavioural support in conjunction with pharmacotherapy as part of their quit attempt.
- NRT, varenicline and bupropion should not be used in combination.

PACEF Recommendation

(9)The majority of people requiring NRT as part of a smoking

combination with an immediate release, short-acting product to counteract cravings. Where short-acting NRT products are prescribed as monotherapy, the maximum dose for each product is as stated in the *BNF* and product SPC. When a short-acting NRT product is used in combination with a long-acting nicotine transdermal patch, the maximum dose of the short acting product should be reduced to half the stated maximum dose. Combination NRT prescribing should never involve more than two formulations, one long-acting and one short-acting.

Transdermal patches

There are a variety of patches licensed for use over 16 or 24 hours. The 24 hour patch is more suitable for:

- Heavily dependent smokers usually requiring their first cigarette within a few minutes of waking.
- Shift workers, particularly those with unpredictable work patterns.

The 16 hour patch is more suitable for:

- Those who crave their first cigarette at least 1 hour after waking.
- Patches licensed for use over 24 hours can be used for patients requiring 16 hour cover if the person is advised to remove them at bedtime.

A common adverse effect of nicotine is sleep disturbance and, for the majority of people, the 16 hour patch is the most appropriate. Local prescribing data indicates that the 16 hour patches are the most frequently prescribed.

The strength of the patch prescribed is usually dependent upon the person's past smoking habit, with the strength of the patch reduced over time. Patches should be applied daily, normally in the morning, to a clean dry, non-hairy area of skin on the hip, trunk or upper arm. Patch sites need to be rotated to avoid skin irritation. Patches should not be applied to broken or inflamed skin and are unsuitable for those with skin disorders. Local experience suggests that *Niquitin* clear patches may be preferred in people who suffer from skin problems. Where transdermal patches are used within this context, the patch should only be applied to areas of skin not affected by the skin disorder.

Patches need to be disposed of correctly (i.e. by folding in half) to prevent children and/or pets being accidentally exposed to nicotine.

As illustrated by the table below, patches are comparably priced:

Cost comparison: Nicotine transdermal patches

| Patch | Strength | Cost (£ per 7 patches) |
|------------------------------|------------|------------------------|
| <i>Nicorette Invisipatch</i> | 10mg/16hrs | £9.97 |
| | 15mg/16hrs | £9.97 |
| | 25mg/16hrs | £9.97 or £16.35 for 14 |
| <i>Nicotinell</i> | 7mg/24 hrs | £9.11 |
| | 14mg/24hrs | £9.40 |
| | 21mg/24hrs | £9.97 or £24.51 for 21 |
| <i>Niquitin</i> | 7mg/24 hrs | £9.97 |
| | 14mg/24hrs | £9.97 |
| | 21mg/24hrs | £9.97 or £18.79 for 14 |

Cost per course: Nicotine transdermal patches

| Patch | Number cigarettes/day | Dose regimen | Cost per quit attempt |
|---|-----------------------|--|--|
| <i>Nicorette Invisipatch</i> (16 hour patch) | >10/day | 25mg daily for 8 weeks then 15mg daily for 2 weeks then 10mg daily for 2 weeks (12 weeks) | £119.64 |
| | <10/day | 15mg daily for 8 weeks then 10mg daily for 4 weeks (12 weeks) | £119.64 |
| | Smoking reduction | 25mg daily until smoking <10 cigarettes a day then 15mg daily for 8 weeks then 10mg daily for 4 weeks | £119.64 + |
| <i>Nicotinell</i> (24 hour patch) | >20/day | 21mg/24hrs daily for 3-4 weeks then 14mg/24 hours for 3-4 weeks then 7mg/24 hours for 3-4 weeks. (maximum duration 3 months) | £113.92 (based on 4 weeks use per strength patch) |
| | <20/day | 14mg/24 hrs for 3-4 weeks then 7mg/24 hours for 3-4 weeks. (maximum duration 3 months) | £74.04 (based on 4 weeks use per strength patch) |
| <i>NiQuitin</i> (24 hour patch) | >10/day | 21mg/24hrs daily for 6 weeks then 14mg/24 hours for 2 weeks then 7mg/24 hours for 2 weeks. (maximum duration 10 weeks) | £99.70 |
| | <10/day | 14mg/24hrs daily for 6 weeks then 7mg/24 hours for 2 weeks (maximum duration 8 weeks) | £79.76 |

Short-acting nicotine replacement products

There are a variety of nicotine containing formulations designed to provide a small dose of nicotine to help relieve intense cravings. The quickest acting formulation is the nasal spray, followed by the oral spray. Lozenges release nicotine faster than chewing gum and seem to be a more acceptable formulation for many patients. Choice of adjunct therapy is largely guided by client preference and is influenced by past smoking habits.

All short-acting nicotine replacement products can be used as monotherapy, although national guidance, supported by local data, suggests that higher quit rates are obtained if short-acting products are used in combination with longer-acting

transdermal nicotine patches. If used in combination with a patch, the maximum

recommended dose for each product is half of the maximum recommended dose if used as monotherapy.

Oral products

Examples: chewing gum, lozenges, sublingual tablets, oral film strips, oral or nasal sprays.

Oral products should be used with caution in those with oesophagitis, gastritis or peptic ulcers because, if swallowed, nicotine can aggravate these conditions. Acidic beverages, such as coffee or fruit juice, may decrease absorption through the buccal mucosa and should be avoided for 15 minutes before the intake of oral nicotine replacement therapy.

Chewing Gums

- The recommended dose is one 2mg gum to be chewed when the urge to smoke occurs. The gum should be chewed until the taste becomes strong, and then rested between the cheek and gum; when the taste starts to fade, chew again and repeat the process. One piece of gum used in this way should last for approximately 30 minutes.
- If used as monotherapy, the recommended dose for those smoking fewer than 20 cigarettes per day is 2mg. For those smoking over 20 cigarettes a day, requiring more than 15 pieces of 2mg gum, the 4mg strength should be used; care should be taken not to exceed the maximum dose.
- Prescribing data indicates that chewing gum is not as popular as it used to be, although it is still the short-acting product of choice for some individuals.
- There is some variation in price between the different brands and flavours, although generally the larger pack sizes are the most cost effective options. Smaller pack sizes should be prescribed initially to avoid unnecessary wastage if treatment needs to be changed in the middle of the course.
- Nicotine chewing gum has a very bitter taste that seems most effectively masked by mint flavours, particularly when used in the 2mg strength.
- If used in combination with nicotine patches, the 2mg strength should be used in preference to the 4mg strength. Highly dependent smokers may need the 4mg gum in combination with a nicotine patch
- Chewing gum may not be suitable for denture wearers as it can stick to and damage dentures.

Cost comparison: Nicotine chewing gums

| Product | Strength | Maximum dose if used as monotherapy (halved if used in conjunction with nicotine patches) | Price/pack size |
|----------------|-----------------|--|--|
| Nicorette gum | 2mg | 15 gums/day | Original, freshmint, mint & fresh fruit (mint & fresh fruit 105 pack size only) £3.25 (30), £9.27 (105) £14.82 (210) Icy white £3.42 (20) £9.37 (105) |
| | 4mg | 15 gums/day | Original, freshmint, mint & fresh fruit (mint & fresh fruit 105 pack size only) £3.99(30), £11.30 (105), £18.24 |

| | | | |
|-----------------------|-----------|-------------|--|
| | | | (210) Icy white £11.48 (105) |
| <i>Nicotinell</i> gum | 2mg | 25 gums/day | Mint , fruit £1.45 (12), £2.67 (24), £8.26 (96) Icemint £6.69 (72) Liquorice £2.67 (24), £8.26 (96) |
| | 4mg | 15 gums/day | Mint, rruit £1.57 (12), £3.30 (24), £10.26 (96) Icemint £8.29 (72) Liquorice £3.30 (24), £10.26 (96) |
| <i>Niquitin</i> gum | 2mg & 4mg | 15 gums/day | Mint £1.71 (12), £3.25 (24), £9.97 (96) |

| Product | Max daily dose | Cost /day |
|-----------------------------|-----------------------------|----------------|
| Chewing gums | | |
| <i>Nicorette</i> gum | | |
| original & fresh mint | 15 x 2mg | £1.06 |
| mint & fresh fruit | 15 x 2mg | £1.32 |
| original & fresh mint | 15 x 4mg | £1.30 |
| mint & fresh fruit | 15 x 4mg | £1.61 |
| <i>Nicotinell</i> | | |
| mint ,fruit .liquorice | 25 x 2mg If using 15/day | £2.15 £1.29 |
| ice mint | 25 x 2mg If using 15/day | £2.32 £1.39 |
| mint, fruit. liquorice | 15 x 4mg | £1.60 |
| ice mint | 15 x 4mg | £1.73 |
| <i>NiQuitin</i> | | |
| mint | 15 x 2mg or 15 x 40mg | £1.56 |

PACEF Recommendation:

(11) If nicotine chewing gums are prescribed, mint flavours seem to be more palatable and better tolerated by most people. As a result of this, and in the absence of any clear difference in price between the major brands and flavours, *Nicorette* icy white flavour gum is advocated as the first line product of choice and is approved for inclusion in the *Lincolnshire Joint Formulary*; designation GREEN.

Lozenges and microtablets

Based on current prescribing trends lozenges are a popular formulation of oral short-acting nicotine. One lozenge should be used every 1 to 2 hours when the urge to smoke occurs. The lozenge should be allowed to dissolve in the mouth and periodically moved from one side of the mouth to the other; each lozenge should last for 10 to 30 minutes. The mini-lozenge is currently the most popular formulation as it is much smaller than alternatives, although slightly more expensive. Due to variation in pack size, it is difficult to compare the cost of different products. Generally, it is more cost effective to prescribe in larger packs, particularly where the prescriber can be confident of patient preference. If used in combination with nicotine patches, 1.5mg or 2mg strengths should be used in preference to the 4mg.

Oral dispersible films (NiQuitin Strips)

There is currently only one oral dispersible film holding a UK marketing authorisation, *NiQuitin Strips*. PACEF evaluated the product in January 2014 and did not consider the available evidence sufficient to support inclusion in the *Lincolnshire Joint Formulary*. As a result of this, nicotine 2.5mg orodispersible film (*NiQuitin Strips Mint*) is designated RED-RED and should not be prescribed.

Cost comparison: Nicotine lozenges, microtablets and oral dispersible films

| Product | Strength | Maximum dose | Price/pack size |
|--|-------------|--------------------|---|
| Lozenges/micro tablets | | | |
| <i>Nicorette Cools</i> (lozenges) | 2mg | 15 lozenges/day | Mint £3.18 (20), £11.48(80) |
| | 4mg | 15 lozenges/day | Mint £11.48 (80) |
| <i>Nicorette Microtab</i> (sublingual) | 2mg | 40tabs/day | £4.83 (30),£13.12 (100) |
| <i>Nicotinell Lozenge</i> | 1mg | 30 mg/day (30 loz) | Mint £1.71 (12), £4.27 (36), £9.12 (96) |
| | 2mg | 30mg/day(15 loz) | Mint £1.99 (12), £4.95 (36), £10.60(96) |
| <i>NiQuitin Lozenge</i> | 2mg & 4 mg | 15 lozenges/day | Original & mint £5.12 (36) £9.97 (72) |
| <i>NiQuitin Minis Lozenge</i> | 1.5mg & 4mg | 15 lozenges/day | Mint & Cherry £3.18 (20), £8.93 (60) |
| <i>NiQuitin Strips</i> orodispersible film | 2.5mg | 15 films /day | £3.51 (15),£10.85 (60) |

Cost per day of treatment: Nicotine lozenges, microtablets and oral dispersible films

| Product | Max daily dose | Cost /day |
|----------------------------|---------------------------|--------------|
| Lozenges/micro tabs | | |
| <i>Nicorette</i> | | |
| lozenges | 15 x 2mg or 15 x 4mg | £2.15 |
| Microtabs | 40 x 2mg | £2.25 |
| <i>Nicotinell</i> | | |
| Lozenge | 30 x 1mg | £2.85 |
| Lozenge | 15 x 2mg | £1.66 |
| <i>NiQuitin</i> | | |
| Lozenge | 15 x 2mg, 15 x 4mg | £2.08 |
| <i>Minis Lozenge</i> | 15 x 1.5mg, 15 x 4mg | £2.23 |
| Orodispersible film | 15 x 2.5mg | £3.15 |

PACEF Recommendation

(12) *NiQuitin Lozenge* 2mg and 4mg and *NiQuitin Minis Lozenges* 1.5mg and 4mg are advocated first line where a short-acting lozenge is indicated. Both formulations are approved for inclusion in the *Lincolnshire Joint Formulary* and designated GREEN. *NiQuitin* orodispersible film 2.5mg has already been evaluated by PACEF and designated RED-RED. It is not approved for use through the *Joint Formulary* and should not be prescribed. Due to current supply problems with *NiQuitin Minis*, *Nicorette Cools* 2mg and 4mg are also designated GREEN and included in the *Lincolnshire Joint Formulary*.

Oral sprays, nasal sprays and inhalators

Nicotine oral spray (Nicorette QuickMist): patients can use one or two sprays into the mouth when the urge to smoke occurs or to prevent cravings. The spray should be released into the mouth, holding the spray as close to the mouth as possible and avoiding the lips. The patient should not inhale whilst spraying and avoid swallowing for a few seconds after use. Patient experience suggests that some patients have difficulty with this technique and can experience a gagging sensation. Directing the spray to the side of the mouth can help to avoid this. Oral sprays should be used with caution in those with oesophagitis, gastritis or peptic ulcers because, if swallowed, nicotine can aggravate these conditions.

Nicotine inhalation cartridges (Nicorette Inhalator): the cartridges can be used when the urge to smoke occurs or to prevent cravings. The cartridge is inserted into the device and air is drawn in through the mouth piece with each use of the device lasting for approximately 5 minutes. The amount of nicotine from 1 puff of the cartridge is less than that from a cigarette and it is likely to be necessary for the person to inhale more frequently than when smoking. A single 15mg cartridge lasts for approximately 40 minutes of intense use. Care should be taken with the inhalation cartridges in those with obstructive lung disease, chronic throat disease or bronchospastic disease. The *Nicorette Inhalator* is the only option that directly mimics the physical activity of smoking. Anecdotal reports indicate that many patients continue to use the inhalator as a habit substitute even after the cartridge is empty.

Nicotine nasal spray (Nicorette Nasal Spray): one spray can be used in each nostril when the urge to smoke occurs up to a frequency of twice an hour. If lower doses are required the spray can be applied to just one nostril. The nasal spray can cause worsening of bronchial asthma and is associated with sneezing and local irritation.

Cost comparison: oral sprays, nasal sprays and inhalators

| Product | Strength | Maximum dose | Cost |
|---|-------------|---|---|
| <i>Nicorette Nasal Spray</i> | 500mcg/dose | 1 spray into each nostril each nostril twice an hour maximum 64 spray/day | £13.40 (10ml – 200 doses) |
| <i>Nicorette QuickMist</i> oromucosal spray | 1mg/dose | Maximum 4 sprays an hour, 64 sprays/day. | 1x 13.2ml £12.12 2X13.2ml £19.14 |
| <i>Nicorette Inhalator</i> inhaler plus cartridge | 15mg | 6 cartridges/day | 4 x £4.14 20 x £14.03 36 x £23.33 |

PACEF Recommendation

(13) Nicotine oral sprays, nasal sprays and inhalators are relatively high cost in comparison with other formulations of NRT. *Nicorette QuickMist* oromucosal spray and *Nicorette Inhalator* are approved for use through the *Lincolnshire Joint Formulary* and are designated GREEN; they should only be prescribed for those who have previously failed to quit using other forms of NRT. *Nicorette Nasal Spray* is not approved for inclusion in the *Joint Formulary* and should not be prescribed.

Electronic cigarettes

Electronic cigarettes (or e-cigarettes) are battery powered devices that deliver on inhalation a vaporised liquid nicotine solution. Each device is comprised of a battery, atomiser and cartridge containing water, propylene glycol or glycerine, varying amounts of nicotine and flavourings such as tobacco, whisky, bubble-gum or fruit. When the user inhales, a sensor detects the airflow and heats the liquid nicotine filled cartridge to produce the vapour. This has led to the term “vaping” being used to describe the use of e-cigarettes.

Electronic cigarettes mimic a real cigarette in design, often having a ‘lit’ end to resemble a lit cigarette and emit a ‘smoke like’ vapour when the user exhales. Despite this resemblance, they do not contain tobacco, don’t burn and therefore do not produce tobacco smoke.

Studies undertaken to date suggest that electronic cigarettes are less harmful than smoking conventional cigarettes. The British Medical Association (BMA) advises that “while e-cigarettes are unregulated and their safety cannot be assured, they are likely to be a lower risk than continuing to smoke.” However, as yet there has been no research to assess the long term health effects of using electronic cigarettes.

At present these products are unlicensed and unregulated; there may be vast differences between brands. In particular, some brands have been found to be of poor quality and ineffective at delivering the nicotine vapour; this means the user could inhale too much or too little nicotine. While cartridges are available in a range of different nicotine strengths; some studies have found that the actual nicotine level does not correspond to that advertised. This may lead to users inhaling more or less nicotine than expected. There have also been some incidents reported in the media where e-cigarette batteries have exploded or started fires.

The MHRA announced in June 2013 a government intention to regulate electronic cigarettes and other nicotine containing products (NCPs) as medicines. There is an expectation that the first NCPs will be regulated as early as 2014.

PACEF Recommendation

(14) Electronic cigarettes are currently not classed as medicines and therefore do not have to comply with the same regulatory standards as licensed nicotine replacement therapies. There are reports that the quality and nicotine content of these products varies widely between brands. There is only limited evidence of effectiveness in supporting a smoking cessation attempt, although some patients are being supported to stop smoking using electronic cigarettes through the Phoenix service. In most cases where the person wants to stop smoking, evidence based pharmacotherapy using licensed NRT products, varenicline or bupropion is preferred.

Acknowledgements

Many thanks to:

Tracey Matthewman, Amanda Richardson, Georgina Barclay, and Carol Johnson from the Phoenix Stop Smoking Service, Lincolnshire Community Health Services. and Phil Garner and Ros Watson from Lincolnshire County Council for their help in the compilation of this *Bulletin*.

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Prepared by:

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Stephen Gibson
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October 2014

References

1. National Institute for Clinical Excellence (NICE) Quality Standard 43 - *Smoking cessation: supporting people to stop smoking* (August 2013)
2. NICE Public Health Guidance 45 - *Tobacco: harm-reduction approaches to smoking* (June 2013).
3. NICE Public Health Guidance 10 - *Smoking cessation services in primary care, pharmacies, local authorities and workplaces, particularly for manual working groups, pregnant women and hard to reach communities* (February 2008).
4. Phoenix Pharmacotherapy Protocol May 2011. To be reviewed June 2014.
5. NHS Nottingham Health Community, *Smoking Cessation Algorithm*.
6. *Guidelines for the prescribing and administration of smoking cessation pharmacotherapy on inpatient wards*.
7. *Standard Treatment programme – one to one smoking cessation programme*. Andy McEwan. 2011. NHS centre for Smoking Cessation and Training.
8. Lincolnshire Stop Smoking Services, *Service Delivery and monitoring guidance 2011/12*.
9. *MIMS* (June to August 2014).
10. National Centre for Smoking Cessation and Training, *Electronic cigarettes* (2014)

Equality Analysis: Initial Assessment Form

Title: Smoke Free Policy

Describe the function to which the Equality Analysis Initial Assessment applies:

- | | | |
|--|---|--|
| <input type="checkbox"/> Service delivery Policy | <input type="checkbox"/> Service improvement Strategy | <input type="checkbox"/> Service change Procedure/Guidance |
| <input type="checkbox"/> Board paper | <input type="checkbox"/> Committee / Forum paper | <input type="checkbox"/> Business case |

Other (please specify)

| | |
|--|----------------------|
| Is this assessment for a new or existing function? | New |
| Name and designation of function Lead professional: | Stephen Kelly |
| Business Unit / Clinical Directorate: | HR & OD |

What are the intended outcomes of this function? *(Please include outline of function*

objectives and aims):

United Lincolnshire Hospitals NHS Trust (ULHT) as a healthcare provider and major employer in Lincolnshire will set an example to other organisations, promote public health and create an environment that minimises the health risks to members of the public, patients and staff who access or provide our services by providing a smoke free Trust environment.

Who will be affected? Please describe in what manner they will be affected?

| Patients / Service Users: | Staff: | Wider Community: |
|--|---|---|
| Patients will not be permitted to smoke on Trust premises. | Employees will not be permitted to smoke on Trust premises. | Visitors contractors and members of the public will not be permitted to smoke on Trust premises |

What impact is the function expected to have on people identifying with any of the protected characteristics (below), as articulated in the Equality Act 2010? (Please tick as appropriate)

| | Positive | Neutral | Negative | Please state the reason for your response and the evidence used in your assessment. |
|---------------------|----------|---------|----------|--|
| Disability | Yes | | | ULHT will actively encourage Health and wellbeing in promoting and supporting smoking cessation. |
| Sex | Yes | | | ULHT will actively encourage Health and wellbeing in promoting and supporting smoking cessation |
| Race | Yes | | | ULHT will actively encourage Health and wellbeing in promoting and supporting smoking cessation |
| Age | Yes | | | ULHT will actively encourage Health and wellbeing in promoting and supporting smoking cessation |
| Gender Reassignment | Yes | | | ULHT will actively encourage Health and wellbeing in promoting and supporting smoking cessation |
| Sexual Orientation | Yes | | | ULHT will actively encourage Health and wellbeing in promoting and |

| | | | | |
|------------------------------|-----|--|--|---|
| | | | | supporting smoking cessation |
| Religion or Belief | Yes | | | ULHT will actively encourage Health and wellbeing in promoting and supporting smoking cessation |
| Pregnancy & Maternity | Yes | | | ULHT will actively encourage Health and wellbeing in promoting and supporting smoking cessation |
| Marriage & Civil Partnership | Yes | | | ULHT will actively encourage Health and wellbeing in promoting and supporting smoking cessation |
| | | | | |
| Carers | Yes | | | ULHT will actively encourage Health and wellbeing in promoting and supporting smoking cessation |

If the answer to the above question is a predicted negative impact for one or more of the protected characteristic groups, a full Equality Analysis must be completed. (The template is located on the Intranet)

| | |
|--|--|
| Name of person/s who carried out the Equality Analysis Initial Assessment: | Stephen Kelly |
| Date assessment completed: | 6th of November 2017 |
| Name of function owner: | |
| Date assessment signed off by function owner: | |
| Proposed review date (please place in your diary) | |

As we have a duty to publicise the results of all Equality Analyses, please forward a copy of this completed document to tim.couchman@ulh.nhs.uk.

Referenced Documents

References

The Health Act 2006, Department of Health

NICE Guideline on Quitting Smoking in Pregnancy and following Childbirth. (PH 26), June 2010

NICE Guideline on Smoking cessation in Secondary care: acute, maternity and mental health services. (PH 48), November 2013

British Thoracic Society Smoking Cessation information <https://www.brit-thoracic.org.uk/clinical-information/smoking-cessation/>

Smoking Kills - A White Paper on Tobacco
<https://www.gov.uk/government/publications/a-white-paper-on-tobacco>

Healthy Lives, Healthy People <https://www.gov.uk/government/publications/healthy-lives-healthy-people-our-strategy-for-public-health-in-england>

WHO Framework on Tobacco Control Report on Electronic Nicotine Delivery Systems – July 2014. http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_10-en.pdf

Schraufnagel *et al* (2014) Electronic cigarettes: A position statement of the Forum of International Respiratory Societies. *AJRCCM*. 190(6): 611-618.

Signature Sheet

Names of people consulted about this policy:

| Name | Job title | Department |
|------|-----------|------------|
| | | |
| | | |
| | | |
| | | |
| | | |

| Names of committees which have approved the policy | Approved on |
|--|-------------|
| Trust Health and Safety Committee | |
| Staff Engagement Group (SEG) | |
| | |